



FEB 06 2009

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph C. O'Neal, President
Progressive Laboratories, Inc.
1701 West Walnut Hill Lane #100
Irving, Texas 75038

Ref. No. CFSAN-OC-UL09-07

Dear Mr. O'Neal:

This is to advise you that in January 2009 the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.progressivelabs.com> and has determined that the product "Probiotic MPF" is promoted for conditions that cause the product to be a drug under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Probiotic MPF

The page on your web site where Probiotic MPF is sold includes the following claims for two substances that are described as nutrients contained in the product.

- "Gamma Oryzanol is used in treating ... stress-induced gastric and duodenal ulcers."
- "Zinc Picolinate accelerates wound healing dramatically and has been particularly effective when used to accelerate healing of gastric ulcers. By strengthening the cell walls, it helps protect the mucous membrane against invading bacteria."

Your product is not generally recognized as safe and effective for the above referenced uses and, therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention of disease are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html> (codified at 21 C.F.R. § 101.93(g)).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 of the Code of Federal Regulations (21 C.F.R.) Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. You may respond in writing to Latasha Robinson, Compliance Officer, Food and Drug Administration, Office of Compliance, Division of Enforcement, Labeling Compliance Team (HFS-608), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition